UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,234	01/13/2005	Satoshi Yonehara	10873.1574USWO	8752

7590 11/30/2009

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. BOX 2902-0902
MINNEAPOLIS, MN 55402

EXAMINER	
ARIANI, KADE	
ART UNIT	PAPER NUMBER
1651	
MAIL DATE	DELIVERY MODE
11/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/521,234	**Applicant(s)** YONEHARA ET AL.	
	Examiner Kade Ariani	**Art Unit** 1651	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 October 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *11, 14 and 15*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Continuation of 11. does NOT place the application in condition for allowance because:

Regarding Information Disclosure Statement: Stennicke et al. reference is considered.

The objection to claim 15 is withdrawn.

Attachment to the Advisory Action:
Applicant argument filed on 10/22/2009, has been considered but is not found persuasive.
Applicant argues that the rejection is relying on the improper use of hindsight in the interpretation of the reference.
In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).
In this case, Komori et al. teach a method of measuring the amount of a glycated protein in a sample (Abstract, and page 2 0003 and 0004), pre-treating a sample with a tetrazolium compound (a nitro compound) to eliminate the influence of any reducing substance present in blood which may reduce hydrogen peroxide and inhibit the redox reaction (page 2 0010, 0005, and 0010, page 3 0017, page 6 0045, page 7 0061). Komori et al. also teach the whole blood sample has been hemolyzed in the presence of a surfactant (p.5 0043). Komori et al. teach the pretreated sample is treated with a protease (p.6 0050) (treating a sample containing the glycated protein with a protease in the presence of a sulfonic acid compound) (page 6 0045, page 7 0061). Komori et al. further teach a protease and degrading the glycated protein by a fructosyl amino oxidase to form hydrogen peroxide and measuring the quantity of hydrogen peroxide by measuring the degree of the color (0004, 0030, 0051) using a spectrophotometer (0059).
Komori et al. do not teach the sulfonic acid compound is 4-aminoazobenzene-4-sulfonic acid sodium, the nitro compound is 2, 4-dinitrophenol, and the protease is a metalloproteinase. However, Bauman et al. teach 4-aminoazobenzene-4-sulfonic acid sodium salt or 4-aminoazobenzene-4- sodium sulfonate (AABSS) is a surfactant (column 4 lines 66-67 and column 5 lines 12-13).
Moreover, Ledis et al. teach using sulfonic acids and a nitro compounds for hemolysis of a whole blood sample (column 5 lines 64-66), sulfonic acids including benzenesulfonic acid (column 6 line 42-44), and nitro compound with an electron withdrawing group, the nitro compound 2,4-dinitrophenol for hemolysis of red blood cells (erythrocytes) of a whole blood sample (column 6 lines 55-60).
It must be noted that a person of ordinary skill in the art at the time the invention was made, would have realized that a reducing agent is a substance that reduce another substance by supplying electrons to it, and compounds with electron withdrawing groups (in this case nitro compound 2, 4-dinitrophenol) are oxidizing substances which are able to remove electrons from reducing agents.
Furthermore, Ishimaru et al. teach measuring an amount of a glycated protein in a sample by treating the glycated protein with Protease N (a metalloproteinase) (Abstract and Col.11, Table 2) in order to enhance the sensitivity of the detection (Col.5, Lines 59-63).
Therefore, in view of the above teachings, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute the surfactant in the method of Komori et al. for the 4-aminoazobenzene-4-sulfonic acid sodium salt (surfactant) as taught by Bauman et al., to provide a method of measuring an amount of glycated protein with a predictable results of hemolzying the whole blood sample, because substitution of one known surfactant with another known surfactant would have provided predictable result to a person of ordinary skill in the art at the time the invention was made.
Moreover, a person of ordinary skill in the art at the time the invention was made, recognizing that the reducing substances present in blood may reduce hydrogen peroxide and inhibit the redox reaction, would have been motivated to substitute the nitro compound (tetrazolium) for the nitro compound 2,4-dinitrophenol with electron withdrawing group (oxidizing agent) according to the teachings of Ledis et al. and Komori et al. to provide a method of measuring the amount of a glycated protein with predictable results of eliminating the effect of reducing agents in the sample, because Ledis et al. teach the nitro compound 2,4-dinitrophenol has electron withdrawing group, and because substitution of one known oxidizing agent with another would have given predictable results to a person of ordinary skill in the art at the time the invention was made.
Moreover, a person of ordinary skill in the art at the time the invention was made, would have been motivated to substitute the protease in the method of Komori et al. for the protease as taught by Ishimaru et al. with a reasonable expectation of success in obtaining a glycated protein degradation product, because Ishimaru et al. teach treating the glycated protein with a metalloproteinase to measure an amount of a glycated protein in a sample. The motivation as taught by Ishimaru et al. would be to enhance the sensitivity of the detection. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. KSR, 550 U.S. at 398 (2007) , 82 USPQ2d at 1395; Sakraida v. AG Pro, Inc., 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); Anderson 's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).